

# Quantification of Congenital Heart Disease Surgical Outcomes 2012-2015: a Four-Year Experience with the International Quality Improvement Collaborative Program

*Cuantificación de resultados en cirugía de cardiopatía congénita 2012-2015: cuatro años de experiencia con el programa colaborativo internacional de mejoría de calidad*

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## ABSTRACT

**Background:** The health care system is having increasing interest in crossing the quality chasm. Surgery for congenital heart defects has improved in terms of outcomes and quality of life; however, the risk of mortality and infection needs to be quantified. The goal of this study was to quantify surgical outcomes of congenital heart diseases following the International Quality Improvement Collaborative (IQIC) for Congenital Heart Disease program with the aim of improving them.

**Methods:** This observational and interventional study, including patients undergoing surgery for congenital heart defects between January 1, 2012 and December 31, 2015, was conducted at a tertiary children's hospital in Cordoba, Argentina. The following variables were quantified: sex, age, weight, complexity-adjusted risk, unadjusted risk, standardized in-hospital mortality and infection ratios (observed rate/expected rate) with their corresponding 95% confidence intervals. The results were compared with the IQIC program benchmarks (1.0 = benchmarking data, <1 = quality improvement). The IQIC guidelines based on 3 key drivers: safe perioperative practice, reduction of infections and team-based practice were implemented as intervention for improvement.

**Results:** A total of 373 surgical procedures for congenital heart defects were performed on 203 male and 170 female patients classified in Risk Adjustment for Congenital Heart Surgery-1 (RACHS-1) risk categories.

The six-monthly unadjusted mortality was 6%, 3%, 8%, 9%, 11%, 0%, 0% and 5%, respectively (benchmarking data 4-6%).

The standardized in-hospital mortality ratios and their corresponding confidence intervals were 0.85 (0.23-2.18), 1.82 (0.79-3.59), 1.07 (0.39-2.34), and 0.36 (0.04-1.29), respectively.

The six-monthly unadjusted infection was 24%, 23%, 25%, 14%, 13%, 6%, 9% and 16%, respectively (benchmarking data 5-7%).

The standardized infection ratios and their corresponding confidence intervals were 1.89 (1.12-2.99), 1.87 (1.17-2.83), 2.0 (1.20-3.12), 1.22 (0.61-2.18), respectively.

**Conclusions:** The implementation of the IQIC program for congenital heart diseases in a public tertiary hospital in Cordoba, Argentina, contributed to quantify outcomes and introduce guidelines to improve them. While mortality decreased, the rate of infections needs still to be improved.

**Key words:** Heart Defects, Congenital - Cardiovascular Diseases/surgery - Quality Improvement - Quality Indicators, Health Care - Cardiovascular Surgical Procedures-

## RESUMEN

**Introducción:** El sistema de salud experimenta un creciente interés en cruzar el abismo de calidad. La cirugía de cardiopatías congénitas ha mejorado en resultados y calidad de vida; no obstante tiene riesgo de mortalidad e infección que requieren cuantificación. El objetivo de este trabajo fue cuantificar sus resultados a través del Programa Colaborativo Internacional para Mejoría de Calidad en cirugía de cardiopatías congénitas con el propósito de mejorarlos.

**Material y métodos:** Estudio prospectivo intervencionista, en Hospital Público Terciario de Niños, Córdoba, Argentina. Se incluyeron pacientes con cirugía de cardiopatías congénitas desde el 1 de enero de 2012 al 31 de diciembre de 2015; se cuantificó sexo, edad y peso en cirugía de cardiopatías congénitas, riesgo ajustado a complejidad, porcentaje no ajustado e índices estándar de mortalidad intrahospitalaria e infección estándar (índice observado/índice esperado) con intervalos de confianza del 95% y se comparó con el estándar del Programa Colaborativo para Mejoría de Calidad (1,0 = estándar, < 1 = mejoría). Como intervención se introdujeron las guías conductoras: prácticas perioperatorias seguras, control de infección y trabajo en equipo.

**Resultados:** Se efectuaron 373 cirugías de cardiopatías congénitas en 203 varones, 170 mujeres con porcentajes de riesgo ajustado a cirugía de cardiopatía congénita (RACHS-1).

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El porcentaje semestral de mortalidad no ajustado fue del 6%, 3%, 8%, 9%, 11%, 0%, 0% y 5%, respectivamente (estándar 4-6%).

El índice estándar de mortalidad intrahospitalaria y el intervalo de confianza fueron 0,85 (0,23-2,18), 1,82 (0,79-3,59), 1,07 (0,39-2,34), 0,36 (0,04-1,29), respectivamente.

El porcentaje semestral de infección no ajustado fue 24%, 23%, 25%, 14%, 13%, 6%, 9% y 16%, respectivamente (estándar 5-7%).

El índice de infección estándar y el intervalo de confianza fueron 1,89 (1,12-2,99), 1,87 (1,17-2,83), 2,0 (1,20-3,12), 1,22 (0,61-2,18).

**Conclusiones:** La implementación del Programa Colaborativo para Mejoría de Calidad en cirugía de cardiopatías congénitas del Hospital Público Terciario de Niños, Córdoba, Argentina contribuyó a cuantificar resultados e introducir la implementación de guías conductoras para mejorarlos. Se logró la reducción en mortalidad, en tanto la infección continúa por mejorar.

**Palabras clave:** Cardiopatías Congénitas - Enfermedad cardiovascular/cirugía - Mejoramiento de la Calidad - Indicadores de Calidad de la Atención de Salud - Procedimientos Quirúrgicos Cardiovasculares

## Abbreviations

|             |                                                          |                |                                                |
|-------------|----------------------------------------------------------|----------------|------------------------------------------------|
| <b>CHD</b>  | Congenital heart disease                                 | <b>PNCC</b>    | National Congenital Heart Disease Program      |
| <b>CI</b>   | Confidence interval                                      | <b>RACHS-1</b> | Risk Adjustment for Congenital Heart Surgery-1 |
| <b>HNCA</b> | Hospital de Niños Santísima Trinidad, Córdoba, Argentina | <b>SIR</b>     | Standardized infection ratio                   |
| <b>IQIC</b> | International Quality Improvement Collaborative          | <b>SMR</b>     | Standardized mortality ratio                   |

## INTRODUCTION

With the publication “Crossing the Quality Chasm: A New Health System for the 21st Century”, the Institute of Medicine of the United States strongly criticized the past and present health care process, which includes poor communication, lack of interdisciplinary team care and decision-making based on individual preferences, and called for narrowing the gap between the observed and expected health care quality. (1)

The implementation of surgical programs for congenital heart diseases (CHD) can save many lives which would be otherwise lost. (2)

In 2000, a disparity in the opportunities for accessing CHD surgery was observed in Argentina, since 1,100 children died per year of CHD, 490 of them in the neonatal period. (3)

In response to this evidence, the National Congenital Heart Disease Program (PNCC) was developed in 2006 with the vision of organizing, categorizing and training public hospitals with capability for CHD surgery nationwide, and the mission of reducing the surgical waiting list and mortality due to CHD. The program was launched in 2010. (4)

Thus, the access of patients with CHD to public hospitals increased in a population with limited resources in whom survival could depend on malnutrition and other morbidities.

The risk of mortality and infection associated with surgery for CHD needs evidence of sequential quantification in order to improve the outcomes by means of multidisciplinary health care teams and institutional commitment. (2)

In 2010, the International Quality Improvement Collaborative (IQIC) for Congenital Heart Disease program for developing countries, promoted by Boston Children’s Hospital, Harvard University, began to enroll institutions that endorsed these goals. (5)

The aim of this study was to quantify the outcomes of CHD surgery through the IQIC for Congenital Heart Disease program to improve them.

## METHODS

We conducted an interventional and prospective study at Hospital de Niños Santísima Trinidad, Córdoba, Argentina (HNCA), a tertiary children’s hospital belonging to the PNCC, categorized as a reference and treatment hospital. (4)

All the patients undergoing CHD surgery reported to the PNCC and referred to the HNCA were included in the study, and the information was loaded into the online IQIC database between January 1, 2012, and December 31, 2015. The following variables were quantified: sex, age, weight and the risk-adjustment for congenital heart surgery (RACHS-1) risk categories, and every six months, the unadjusted by RACHS-1 risk of in-hospital mortality and infection due to CHD surgery were estimated and compared with the IQIC for Congenital Heart Disease program benchmarking data of all the 47 participating centers for the period 2012-2015.

The standardized in-hospital mortality ratio (SMR) and standardized infection ratio (SIR) (observed rate/expected rate) with their corresponding 95% confidence intervals (CI) were quantified per year, where 1.0 = IQIC benchmarking data, and <1.0 = quality improvement.

The IQIC guidelines, based on three key drivers, safe perioperative practice, reduction of infection and team-based practice, were implemented as interventions for improvement. RACHS-1-adjusted and unadjusted mean in-hospital and 30-day mortality rate and infection rate were quantified during the period 2012-2015.

## Statistical analysis

We calculated SMR and SIR obtained as the result of observed/expected mortality and observed /expected infection, respectively.

Expected mortality and expected infection were obtained from mean mortality/infection for similar cases in the IQIC database with multiple regression analysis of the following variables: RACHS-1 risk category, age, prematurity, associated non-cardiac structural anomaly, multiple cardiac procedures, nutritional status, major chromosomal abnormalities and oxygen saturation.

A SMR or SIR equal to 1 indicates “average” mortality compared with the benchmark; a SMR or SIR less than 1 indicates quality improvement and an SMR or SIR greater than 1 indicates that the result is worse than that of the benchmark.

The corresponding 95% confidence intervals (95% CI) were calculated; if the SMR and SIR CI includes relative risk = 1.00, the result is not significant; while a CI not including relative risk = 1.00 means that the result is statistically significant.

### Ethical considerations

Patients' parents or legal guardians gave their consent before surgery. Patients' identity was protected with a nine-digit sequential number code.

The study protocol was approved by the Institutional Ethics Committee.

### RESULTS

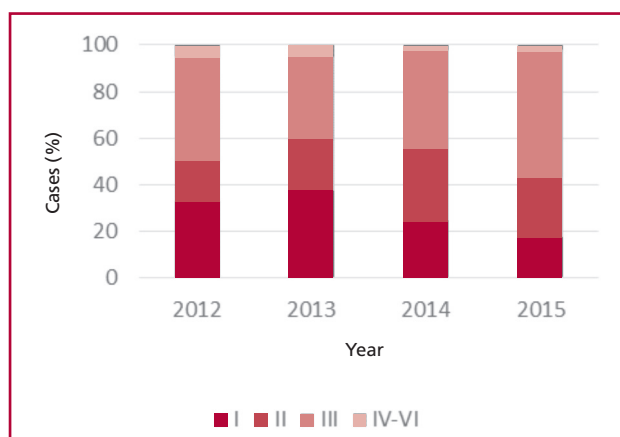
A total of 373 surgeries for CHD were performed with an average of 93 procedures (80-107) per year in 203 boys and 170 girls. Age was <30 days in 10 patients (2.68%), 31-365 days in 131 (35.12%) and 1-17 years in 232 (62.19%); weight was <2.5 kg in 2%; 2.5-4.9 kg in 20%; 5-9.9 kg in 30% and >10 kg in 48% of patients. Weight was below the 5th percentile in 121 patients (32.4%).

The distribution of CHD surgeries according to RACHS-1 I II, III, IV-VI categories per year are shown in Figure 1. Between 2014 and 2015, the percentage of category II-III procedures increased and those of category I decreased.

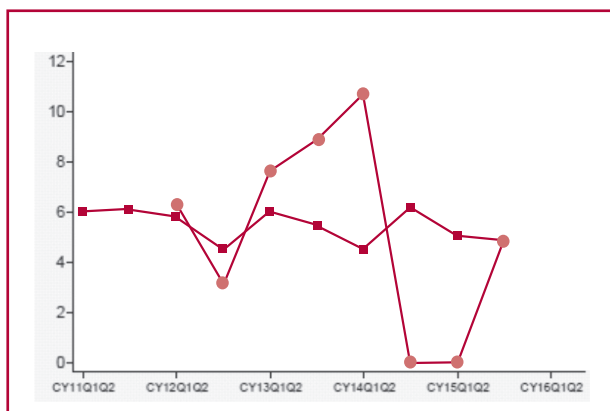
The six-monthly unadjusted mortality for the period 2012-2015 was 6%, 3%, 8%, 9%, 11%, 0%, 0% and 5%, respectively, and the IQIC benchmark was 4-6% in the period analyzed (Figure 2). Mortality rate was 0% in the second semester of 2014 and in the first semester of 2015.

The annual SMR during 2012-2015 was 0.85 (95% CI: 0.23-2.18), 1.82 (95% CI: 0.79-3.59), 1.07 (95% CI: 0.39-2.34) and 0.36 (95% CI: 0.04-0.36), respectively (Figure 3).

Unadjusted mortality for the period 2012-2015 was 5.6% and 5.9% at 30 days, and adjusted mortality rate was 0% for category I RACHS-1, 3.7% for category II, 11.2% for category III and 27.3% for category IV.



**Fig. 1.** Distribution of CHD surgeries according to RACHS-1 categories I, II, III, and IV-VI.



**Fig. 2.** Six-monthly unadjusted mortality rate for the period 2012-2015. ■ All the IQIC participant centers and ● Hospital de Niños.



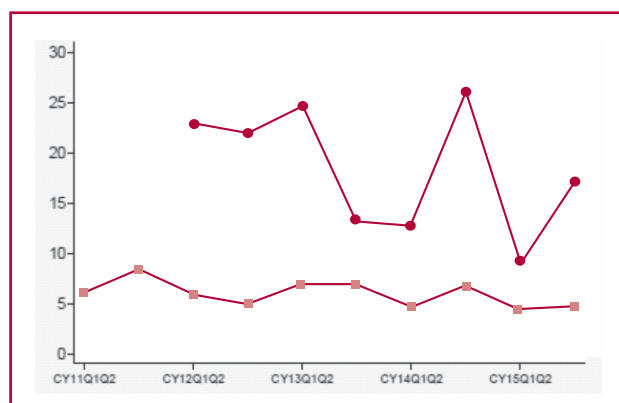
**Fig. 3.** Annual standardized mortality ratio (SMR) during 2012-2015. ● SMR of Hospital de Niños with 95% confidence intervals. The dashed line represents the IQIC benchmark (1.0 = benchmark, < 1 = improvement). SMR increased in 2013 and decreased in 2014-2015.

The six-monthly unadjusted infection rate for the period 2012-2015 was 24%, 23%, 25%, 14%, 13%, 6%, 9% and 16%, respectively, while the IQIC benchmark was 5-7% (Figure 4). The percentage of infection was higher than the benchmark.

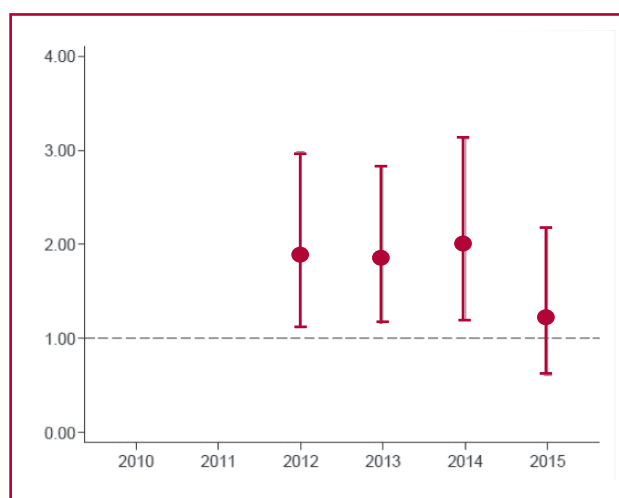
The annual SIR for the period 2012-2015 was 1.89 (95% CI: 1.12-2.99), 1.87 (95% CI: 1.17-2.83), 2.0 (95% CI: 1.20-3.12) and 1.22 (95% CI: 0.61-2.18), respectively (Figure 5).

The unadjusted infection rate for the period 2012-2015 was 19%, with 11.2% for surgical site infection and 8.8% for sepsis, and adjusted infection rate was 8.6% for category I RASCH-1, 16.6% for category II, 34.4% for category III and 36.35% for category IV.

The IQIC conducted an educational program which consisted on monthly telemedicine webinars, international and regional learning sessions and on-site annual audit/visit to address each of the 3 key drivers.



**Fig. 4.** Six-monthly unadjusted infection rate for the period 2012-2015. ■ All the IQIC participant centers and ● Hospital de Niños.



**Fig. 4.** Annual standardized infection ratio (SIR) during 2012-2015. ● Hospital de Niños with 95% confidence intervals. The dashed line represents the IQIC benchmark (1.0 = benchmark, < 1 = quality improvement). The ratio observed was greater than the one expected.

(6) These training sessions were used to change the strategy or to make interventions for quality improvement in: a) safe perioperative practices with the implementation of the recommendations for safe surgical care in the operating room proposed by the World Health Organization and modified by the IQIC, (7-10) and new surgical techniques; b) infection control by applying hand-hygiene checklist, barriers to prevent surgical site, central catheter, urinary catheter and endotracheal tube infection; (11-14) and c) teamwork including nurse empowerment in the cardiovascular intensive care unit and cardiovascular surgery ward, effective multidisciplinary communication during the ward rounds in the cardiovascular intensive care unit, communication via email during CHD surgery ward rounds, surgical scheduling, and meetings of the surgical team to analyze the six-monthly and annual results submitted by the IQIC. (15-20)

## DISCUSSION

There is scarce data about the results in CHD surgery in developing countries. (2) In 2001, unadjusted in-hospital mortality was 4% and adjusted in-hospital mortality was 0.4% for category I RACHS-1, 3.8% for category II, 8.5% for category III, 19.4% for category IV, and 47.7% for category VI. (21)

There is little information about the outcomes with the use of this method in developing countries. Guatemala was the first developing country to report improvement in mortality rate in a cohort of 1,215 CHD surgeries from July 1997 to July 2004. The 1997 to 1999 unadjusted SMR was 10.0 (95% CI, 7.2 to 13.7), indicating a 10-fold increase in death risk compared with the benchmark. In 2000 to 2002, the SMR was 7.8 (95% CI, 5.9 to 10.0) and in 2003 to 2004, it was 5.7 (95% CI, 3.8 to 8.3). When compared against the US benchmark for the year 2000 using the RACHS-1 method, the SMR improved but did not reach such benchmark. (22)

During the 2000-2007 period, HNCA participated in the Pediatric Cardiac Care Consortium, from the University of Minnesota, Minneapolis, and the results were published in 2009. During that period, 637 CHD surgeries were performed (mean volume: 80 surgeries per year); unadjusted mortality rate at 30 days was 12.7% and 15.38% at one year, while adjusted mortality was: 1% for category I RACHS-1, 9.3% for category II, 22% for category III, 32.25% for category IV, and 75% for category VI. When compared with the RACHS-1 benchmark, the results did not reach such standard ( $p < 0.01$ ), except for category I ( $p$ :NS). (23-25)

In 2007, a private institution in Buenos Aires reported the experience with 571 CHD surgeries between March 2001 and March 2007. Unadjusted mortality rate at 30 days was 3.8% and adjusted by RACHS-1, it was 0% for category I, 0.92% for category II, 3.37% for category III, 10.64% for category IV, 0% for category V and 32.14% for category VI. When compared with the RACHS-1 benchmark, this was achieved in all the categories. (26)

In 2014, the IQIC published the results obtained in 2010, 2011 and 2012 from 28 centers (including HNCA in 2012) in 17 developing countries. Among 15,049 CHD surgeries, the unadjusted in-hospital mortality rate was 6.3% and 30-day mortality was 7.4%, and adjusted in-hospital mortality rate was 1.5% in category I RACHS-1, 3.8% in category II, 10.6% in category III, 17.7% in category IV, and 51.1% in categories V and VI combined. The SMR for the 7 centers participating in all 3 years was 0.85 (95% CI 0.71–1.00) in 2011 and 0.80 (95% CI 0.66–0.96) in 2012 compared with the baseline rate in 2010, which implied quality improvement. (10)

The PNCC was launched in 2010. (4) Initially, HNCA quantified the outcomes of CHD surgeries between 2000 and 2007, and participated in the PNCC in 2010. In 2012, the HNCA was included in the IQIC program and quantified the results in terms of in-hos-

pital mortality, 30-day mortality and infection in CHD surgeries in order to improve them.

The vision of the IQIC is to facilitate collaborative work of health care teams from around the world creating a culture of safety and quality of care for CHD surgeries. The IQIC mission is to reduce mortality and major complications for CHD surgeries using a telemedicine platform to facilitate long-distance learning. (5, 6) The program has thus introduced three key drivers: a) safe perioperative practice using a surgical safety checklist and implementation of new surgical techniques b) reduction of infection by implementing barriers to prevent surgical site, central catheter, urinary catheter and endotracheal tube infection, and c) team-based practice through nurse empowerment and effective communication between the cardiovascular surgeons and cardiovascular team.

The HNCA was categorized as a medium-complexity institution due to the number of surgeries performed per year. As the results of the PNCC have not been published yet, in this study we describe the outcomes in terms of mortality and infection of 373 consecutive CHD surgeries performed at HNCA between 2012 and 2015 to quantify the outcomes in order to improve them and establish whether the strategies used could optimize the results.

Thus, six-monthly mortality and SMR were quantified, reaching the benchmark in 2014, and improving to 0.36 ( $<1$  = quality improvement) in 2015, which means that the measures applied were beginning to work (5, 6, 20, 27) and the goal of quality and safety improvement was attained (Figures 2 and 3). The causes of death were attributed to low cardiac output in 75% of cases, infection in 15%, hypoxemia in 5%, and bleeding in 5%. The six-monthly CHD surgical mortality showed a dramatic reduction to 0% during the second semester of 2014 and the first semester of 2015 (Figure 2), probably due to the cardiovascular team training, involving cardiologists, surgeons, anesthesiologists, perfusionists, specialists in critical care and cardiovascular nurses. In the second semester of 2015, the higher mortality was attributed to staphylococcus infection in a patient undergoing successful surgery of Tetralogy of Fallot with 22q11 microdeletion and immunodeficiency, and to postoperative bleeding after surgery for hypoplastic aortic arch in another patient. The results over the 4-year period were averaged, resulting in reduction of in-hospital mortality by categories, with lower percentage than the IQIC, except for category IV ( $p < 0.001$ ). (20)

Thus, once the reduction in mortality was quantified, quality improvement was evident, ensuring patient safety, which is an important component of the healthcare system. (1)

Hospital acquired infections are one of the indicators of morbidity. (28)

The findings described in Figures 4 and 5 about infection related with CHD surgery demonstrate that we did not achieve the benchmark data of developed

countries participating in the IQIC program. Unadjusted infection rate for the period 2012-2015 was 19%, surgical site infection was 11.2% and sepsis 8.8% and adjusted rate infection was 8.6% for category I RACHS-1, 16.6% for category II, 34.4% for category III and 36.3% for category IV. In 2017, The IQIC reported that, for the period 2010-2012, among a total of 14,545 cases, 793 (5.5%) had bacterial sepsis and 306 (2.1%) had surgical site infection. In-hospital mortality was significantly higher among cases with infection than among those without infection (16.7% versus 5.3%;  $p < 0.001$ ). (29) This quantification suggests that the HNCA should make effective interventions to reduce infection.

In a health care system, infection represents longer hospital stay and higher costs; this percentage can be used as an indicator of efficiency in the use of resources. (1)

Every participant in a health care system (patient, family member, physician, program director, hospital administrator, and politician) needs to understand the results of complex treatments as CHD surgery. (21)

#### Study limitations

We did not quantify other variables of morbidity or other components of this health care system, as surgical timing, equity, effectiveness and patient-centered care.

#### CONCLUSIONS

The implementation of the IQIC for Congenital Heart Disease program in HNCA was useful to quantify and improve the CHD surgery outcomes by reducing mortality, while the rate of infection still needs to be improved.

#### Conflicts of interest

None declared.

(See authors' conflicts of interest forms on the website/ Supplementary material)

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